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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/502,664 | 02/11/2000 | Ronald D. Vale | REGEN1500-1 | 5502 |
| 7590 | 07/30/2002 | | | |
| Lisa A Haile Gary Cary Ware & Freidenrich LLP 4365 Executive Drive Suite 1100 San Diego, CA 92121-2133 | | | EXAMINER | |
| | | | ROBINSON, HOPE A | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1653 | | |
| | | DATE MAILED: 07/30/2002 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|-------------------------------|-----------------------------|
| Application No. 09/502,664 | Applicant(s) Vale et al. |
| Examiner Hope Robinson | Art Unit 1653 |



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on May 7, 2002
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1, 3-12, and 104 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3-12, and 104 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

1. Applicant's response to the Office Action mailed November 26, 2001 in Paper No. 15 on May 7, 2002 is acknowledged.
2. Claims 2 and 13-103 have been canceled. Claim 104 has been added. Claims 1, 4 and 8 have been amended. Claims 1, 3-12 and 104 are pending.

Restriction/Election

3. The on page 5 traverses the species election and indicates that no reasoning was provided in Paper No. 6 by the previous examiner. The statements made by applicant have been considered and are persuasive therefore, the species election is hereby withdrawn.
4. The following grounds of rejection are or remain applicable :

Oath/Declaration

5. The newly submitted Oath/Declaration is objected to because the inventor Marija Matuska's citizenship is listed as "German" and the country of citizenship belongs in this

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field, which should be “Germany”, see for example that the “United States” is listed for other inventors instead of “American”.

Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-12 and 104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 remains indefinite with regard to the “solid support” as the claim does not recite the type of “solid support”. The dependent claims are also included in this rejection.

Claim 8 remains rejected as being indefinite because the claims contain the trademark/trade name Nylon TM and Teflon TM. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade

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name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the preparation and, accordingly, the identification/description is indefinite. Regarding claim 8, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. The response filed May 7, 2002 on page 7 contends that claim 1 is definite with regard to "solid support" because a skilled artisan would recognize that the term can refer to any of various different materials such as recited in claim 8. Applicant's contention is precisely why the rejection was made because as the term can represent a variety of different materials the claim needs to specify which one is pertinent to the claimed invention for one of skill in the art to be able to practice the full scope of the claim. Claim 1 needs to stand on its own thus, the dependent claim 8 does not rectify the issue. Regarding claim 8, applicant contends that the trade mark recitation is definite as the claim has been amended to use the recited trademarked names as adjectives, thus preserving their proprietary value (see pages 4 and 7 of the response). However, the rejection remains because the rejection states that "where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph" (emphasis added). Thus applicant's amendment to use the trademark as adjectives does not obviate this ground of rejection as an

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adjective is used to describe a particular material or product. Note the new ground of rejection instituted based on the language of the claim.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4-7 and 9-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsien et al. (U.S. Patent No. 6,008,378, December 28, 1999).

Tsien teach biarsenical molecules and target sequence (FlAsH) see Figure 3. Tsien teaches that the biarsenical molecule preferably is capable of traversing a biological membrane, and includes a detectable group, for example, fluorescent group, luminescent group, phosphorescent group, spin label, photosensitizer, photocleavable moiety, chelating center, heavy atom, radioactive isotope, isotope detectable by nuclear magnetic resonance, paramagnetic atom and combinations thereof (see specification page 4 where the modified FlAsH is defined and claim 1 of the present application). Tsien also teach examples of these groups in Figures 6, 8 and 9 which demonstrates a modified FlAsH (see claim 1). Tsien further teaches that the biarsenical molecule is bonded to a dithiol such as EDT (see claims 9 and 10) and may be coupled to a solid phase (see

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claim 1). In addition, Tsien teaches that the target sequence may be modified by the addition of the motif Cys-Cys-X-Y-Cys-Cys, wherein X and Y are amino acids (the same or different amino acids as in claims 4-7 of the application). The reference teaches that cysteines are positioned for encouraging arsenic interaction across helical turns. Finally, Tsien teaches a polypeptide in solution obtained from cells (from a eukaryote or prokaryote) and that the polypeptide is isolated with the use of FlAsH (see abstract, columns 1-8, claims 10-12 and Example 2 of the reference). Thus, the teachings of the reference anticipates the present claims.

9. Claims 1, 4-7 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al. (Science, vol. 281, pages 269-272, July 10, 1998).

Griffin teach the compound known as FlAsH and that it specifically interacts with proteins tagged with a Cys-Cys-X-X-Cys-Cys containing helix (see claim 1, 4-7). Griffin also teach that the dithiols EDT is used called FLASH-EDT to facilitate purification of the protein (see claims 9-10). Griffin also teaches a method of protein isolation that involves the polypeptide in solution from a eukaryote or prokaryote (claims 11 and 12). As Griffin teaches a method of protein isolation that uses the compound FlAsH in a modified form as claimed, the reference anticipates the claimed invention (see abstract and pages 269-272 of the reference).

10. Applicant's arguments filed May 7, 2002 in Paper No. 15 have been considered. Note that the rejections of record have been maintained under 35 U.S.C. 102. Regarding the rejection using

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the Griffin reference, the specification on page 3 discloses that “recently, a fluorescent dye has been developed which specifically interacts with tetraceysteine containing helices (Griffin, et al., 1998). This compound, known as FlAsH has been shown to specifically interact with proteins tagged with a C-C-X1-X2-C-C containing helix”. The response on page 8 states that “the ‘378 Patent does not teach or suggest a FlAsH compound, which is modified by acylation with an amino acid as required by the claims”. Note that the Griffin reference is an article in Science , vol. 281, 1998 and not a U.S. Patent (‘378 Patent is by Tsien et al.). Therefore, based on the disclosure in the specification, the reasons stated above and because applicant did not provide any arguments as to why the Griffin reference is not relevant, the rejection has been maintained. Regarding the reference by Tsien, U.S. Patent ‘378, applicant states that “the ‘378 Patent does not teach or suggest a FlAsH compound, which is modified by acylation with an amino acid as required by the claims”. Applicant provides no statements to counter the reasoning provided above, for example the reference made to Fig. 3 of the Tsien reference and the disclosure in the specification as to what is considered to be FlAsH. Therefore, applicant’s arguments are not persuasive and the rejection remains.

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Conclusion

11. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday and Wednesday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

Karen Cochrane Carlson Ph.D.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER